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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,587	02/25/2002	Edward J. Gavin	016866-008200US	6008
20350	7590	08/18/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			LAU, TUNG S	
			ART UNIT	PAPER NUMBER
			2863	

DATE MAILED: 08/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,587

Applicant(s)

GAVIN ET AL.

Examiner

Tung S Lau

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7-16-2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION**Double Patenting rejection**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-40 provisionally rejected under the judicially created doctrine of double patenting over claim 1-38 of copending Application No. 09999081. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: analyzes mass spectra using a digital computer, the method comprising: a) entering into a digital computer a data set obtained from mass spectra from a plurality of samples, wherein each sample is, or is to be assigned to a class within a class set comprising two or more classes, each class characterized by a different biological status, and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio; and b) forming a classification

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model which discriminates between the classes in the class set, wherein forming comprises analyzing the data set by executing code that embodies a classification process comprising a recursive partitioning process.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 35, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27, 28, 19, 30, 31, 32, 33, 34, 37, 38, 39, 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Hillenkamp (U.S. Patent 6,558,902).

Regarding claim 1:

Hillenkamp discloses a method that analyzes mass spectra using a digital computer, the method comprising: a) entering into a digital computer a data set obtained from mass spectra from a plurality of samples, wherein each sample is,

or is to be assigned to a class within a class set comprising two or more classes (Col. 43-44, Lines 10-50, Col. 71, Lines 5-46), each class characterized by a different biological status (Col. 69, Lines 5-51), and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio (Col. 44-45, Lines 32-3) using laser ionization desorption process (Col. 4-5, Lines 52-26); and b) forming a classification model which discriminates between the classes in the class set, wherein forming comprises analyzing the data set by executing code that embodies a classification process comprising a recursive partitioning process (Col. 44-45, Lines 32-3, Col. 69, Lines 5-51).

Regarding claim 35:

Hillenkamp discloses a computer readable medium a) code for entering data set obtained from mass spectra from a plurality of samples, wherein each sample is, or is to be assigned to a class within a class set comprising two or more classes (Col. 43-44, Lines 10-50, Col. 71, Lines 5-46), each class characterized by a different biological status (Col. 69, Lines 5-51), and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio (Col. 44-45, Lines 32-3) using laser ionization desorption process (Col. 4-5, Lines 52-26); and b) forming a classification model which discriminates between the classes in the class set, wherein forming comprises analyzing the data set by

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executing code that embodies a classification process comprising a recursive partitioning process (Col. 44-45, Lines 32-3, Col. 69, Lines 5-51).

Regarding claims 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27, 28, 19, 30, 31, 32, 33, 34, 37, 38, 39, 40:

Hillenkamp also disclose the use of MALDI (Col. 4-5, Lines 53-18), class consist of two classes (Col. 71, Lines 5-25), selected from group of Polypeptides and nucleic acids (abstract, Col. 71, Lines 5-24), selected from virus (Col. 69, Lines 13-51), normal and pathological status (Col. 69, Lines 13-51), un-diseased, low and high grade cancer (Col. 1, Lines 24-65), use a drug treated state, drug-responder and non-responder state (Col. 67, Lines 7-15), toxic and non toxic state (Col. 67, Lines 7-15), exposure to drug (Col. 67, Lines 7-15), is a known data set (Col. 69, Lines 13-51), pre-existing marker from classification (Col. 71, Lines 5-46), detecting signal of mass spectra in mass-to charge ratio (Col. 44-45, Lines 34-3), identifying features and different biological status (Col. 69, Lines 13-51), process is binary recursive partitioning process (Col. 78, Lines 34-53), interrogating classification for biological statues, using larger sample (Col. 71, Lines 5-46), use in a gas ion spectrometer (Col. 93-94, Lines 65-11), adopted to perform a laser desorption ionization process (Col. 93-94, Lines 65-11), a surface enhance desorption with antibodies (Col. 13-14, Lines 65-35, Col. 17, Lines 20-36). Using an unknown sample (Col. 64, Lines 36-63); repeat process (Col. 1-2, Lines 40-55); cluster analysis (Col. 91, Lines 18-29); using unknown sample (Col.

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28, Lines 28-49); use of antibodies material (Col. 17, Lines 21-37), function derived from mass to charge ratio (Col. 44, Lines 32-50).

Claim Objections

3. Claims 16, 20, 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitation of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance: prior art fail to teach the use of neural network analysis, using raw data preprocessing.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

4. Applicant's arguments filed 7/16/2004 have been fully considered but they are not persuasive.

A. Applicant argues in the arguments that the prior art does not show the Use of a digital computer. Hillenkamp discloses the use of a digital computer

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In fig. 1, 2, 3. Where the digital computer analyze the sample (finger print of a target DNA sequence) in different intensity/ units vs. m/z (varies from 0-100 intensity/rel unit, and 0-1m/z range). While the meaning of claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allowed. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

A claim is anticipated only if each and every element set forth is found, either expressly or inherently, in a single reference. MPEP 2131 Further, in order to establish that a feature is inherent, the evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art." MPEP §2112, quoting In re Robertson, 49 USPQ2d 1949, 1950-51 (Fed Cir. 1999). In other words, it must be shown that the "allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." MPEP §2112, quoting Ex pane Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). The Action did not fails to use digital computer in the analysis In fig. 1, 2, 3, that Hillenkamp expressly or inherently discloses all the elements of the independent claims. Therefore, the rejections are proper.

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Insufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation. See *Titanium Metal* 778 F.2d. at 782.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tung S Lau whose telephone number is 571-272-2274. The examiner can normally be reached on M-F 9-5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on 571-272-2269. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TL



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